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No. 01-188

In the Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PETITIONER

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HEALTH, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the prior authorization provisions of the Maine Rx Program are consistent with the Medicaid statute.

2. Whether those provisions violate the Commerce Clause of the Constitution.

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

1. a. The Medicaid program, established by Title XIX of the Social Security Act, 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides federal financial assistance to States that elect to pay for medical services on behalf of certain low-income individuals. See *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). The primary purpose of the Medicaid program is to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish * * * medical assistance on behalf of families with dependent children

and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. 1396.

In order to participate in the Medicaid program, a State must submit a plan for medical assistance to the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration), which administers Medicaid on behalf of the Secretary of Health and Human Services (HHS). 42 U.S.C. 1396a (1994 & Supp. V 1999). The state plan specifies, *inter alia*, the categories of individuals who will receive medical assistance under the plan and the specific kinds of medical care and services that will be covered. If the plan is approved by the Secretary, the State is thereafter eligible to be reimbursed by the federal government for a specified percentage of the amounts expended as medical assistance under the state plan. 42 U.S.C. 1396b(a)(1), 1396d(b) (Supp. V 1999).

States enjoy a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. For example, the Medicaid Act does not require States to provide prescription drugs to Medicaid beneficiaries. 42 U.S.C. 1396a(a)(10)(A) (1994 & Supp. V 1999); 42 C.F.R. 440.225. The Medicaid Act does, however, specify certain individuals who are eligible to be Medicaid recipients, and it establishes a number of prerequisites for CMS approval of a State plan. 42 U.S.C. 1396a(a)(1)-(65) (1994 & Supp. V 1999). Participating States are required to make medical assistance available to certain "categorically needy" persons. 42 U.S.C. 1396a(a)(10)(A)(i) (1994 & Supp. V 1999). At a State's option, a State may additionally make medical assistance available to "medically needy" persons. 42 U.S.C.

1396a(a)(10)(C); see also *Atkins* v. *Rivera*, 477 U.S. 154, 157-158 (1986). The Medicaid Act imposes income and resource limitations on many eligibility groups described in the statute. See, *e.g.*, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), (VI), (VII); see also 42 U.S.C. 1396b(f) (1994 & Supp. V 1999).

A state plan also must provide "such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * * as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A) (Supp. V 1999). As particularly relevant here, a State may subject to "prior authorization" any covered outpatient drug. 42 U.S.C. 1396r-8(d)(1)(A). Under a prior authorization program, a State requires, as a condition of coverage or payment for the drug, the prior approval of a covered outpatient drug before it is dispensed. 42 U.S.C. 1396r-8(d)(5). The Act requires that any system providing for such approval must (1) provide a response to a request for prior authorization within 24 hours of the request, and (2) provide for the dispensing of at least a 72-hour supply of the covered drug in an emergency situation. See 42 U.S.C. 1396r-8(d)(5).

b. Congress recognized that the requirements of the Social Security Act "often stand in the way of experimental programs designed to test out new ideas." S. Rep. No. 1589, 87th Cong., 2d Sess. 19 (1962). Accordingly, Congress amended the Act to authorize the Secretary to approve state demonstration projects under various titles of the Act, including Title XIX, which governs the Medicaid program. 42 U.S.C. 1315 (1994 & Supp. V 1999).

A State that wishes to conduct a demonstration project must submit an application to the Secretary. The Secretary may approve an application for a demonstration project if, "in the judgment of the Secretary," the demonstration project "is likely to assist in promoting the objectives" of the applicable programs. 42 U.S.C. 1315(a) (1994 & Supp. V 1999). If the Secretary makes such a determination for a Medicaid demonstration program, he may waive compliance with any of the requirements of 42 U.S.C. 1396a to the extent and for the period he finds necessary to enable the State to carry out the project. 42 U.S.C. 1315(a)(1). Costs of the demonstration project that would not otherwise qualify as state Medicaid expenditures may be regarded as such expenditures, subject to federal matching. 42 U.S.C. 1315(a)(2)(A) (Supp. V 1999).

2. a. This litigation presents a challenge to the prior authorization provisions of the Maine Rx Program, which was enacted in 2000 but has not yet been implemented.[1] The program was established to reduce prescription drug prices for Maine residents. Me. Rev. Stat. Ann. tit. 22 (Maine Act or Act), § 2681 (West Supp. 2001). The program is open to all Maine residents, and is designed to allow enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. *Id.* § 2681(2)(F); Pet. App. 3.

Under the program, the State will reimburse pharmacies for such discounts out of a fund that is supported by rebate payments that the State collects from drug manufacturers. Maine Act § 2681(9); Pet. App. 3. The Act provides that a drug manufacturer that sells prescription drugs in Maine through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the State. Maine Act § 2681(3). The Act directs the Commissioner of the Maine Department of Human Services to negotiate the amount of the rebate required, taking into consideration the rebate calculated under the federal Medicaid rebate program administered by the Secretary of HHS (see 42 U.S.C. 1396r-8(a)-(c)(1994 & Supp. V 1999)) and using his best efforts to obtain an initial rebate amount equal to or greater than that amount. Maine Act § 2681(4).[2]

The Maine Act provides for the public disclosure of the names of manufacturers that do not enter into rebate agreements with the State. Maine Act § 2681(7). And as particularly relevant here, the Act directs the Maine Department of Human Services to "impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." *Ibid.*

b. Petitioner Pharmaceutical Research & Manufacturers of America brought this action in the United States District Court for the District of Maine to challenge, *inter alia*, the prior authorization provisions of the Maine Rx Program. The district court entered a

[1] Other aspects of the Maine Rx Program have been challenged but those challenges are not before this Court. See Pet. App. 5 n.2.

[2] Under the federal rebate program, if the drug in question is either a single source drug or an innovator multiple source drug, the rebate due on each unit paid for under the State plan is generally the difference between the "average manufacturer price" and the manufacturer's "best price," defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States. 42 U.S.C. 1396r-8(c)(1)(A), (B), and (C) and (c)(2). For other drugs, the rebate is 11%. 42 U.S.C. 1396r-8(c)(3). Rebates are calculated and paid on a quarterly basis. 42 U.S.C. 1396r-8(b)(1)-(3), 1396r-8(k)(8).

preliminary injunction barring the enforcement of the prior authorization requirement against any drug manufacturer that does not enter into a rebate agreement with the State. Pet. App. 57-72.

The district court first held that invocation of a prior authorization provision in this manner is inconsistent with the objectives of the Medicaid statute. Pet. App. 66-71. The court explained that the purposes of the Medicaid statute are to provide medical services, including prescription drugs, to individuals who are eligible for Medicaid, and observed that Congress thus has required that a state plan ensure that care and services will be provided "in a manner consistent with the best interests" of Medicaid recipients. *Id.* at 67-68 (quoting 42 U.S.C. 1396a(a)(19)) (emphasis omitted). In the court's view, the prior authorization provisions could not be enforced because Maine could not identify any Medicaid purpose that those provisions would serve. *Ibid.*

The court also concluded that the prior authorization provisions violate the Commerce Clause. Pet. App. 61-66. The court first rejected the argument that Maine was acting as a market participant in enacting and administering the Maine Rx Program, noting that Maine is attempting to influence the terms of transactions to which it is not a party. *Id.* at 62-64. The court then opined that the "practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." *Id.* at 66. The court held that this consequence renders the rebate program an unconstitutional effort to legislate extraterritorially. *Ibid.*

3. The court of appeals reversed and vacated the preliminary injunction. Pet. App. 1-53. After determining that petitioner had standing to sue (*id.* at 6-8), the court rejected its arguments on the merits. The court perceived "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. The court observed that the Medicaid statute authorizes the States to impose prior authorization requirements, as long as a response to a request for authorization to dispense a drug is given within 24 hours and a 72-hour emergency supply is dispensed. *Ibid.* (citing 42 U.S.C. 1396r-8(d)(5)(A) and (B)). In the court's view, the language of the Maine Act directing that prior authorization requirements be imposed "as permitted by law" limits the Maine Act's application to situations in which prior authorization is permitted by Medicaid. *Ibid.* (quoting Maine Act § 2681(7)). The court expressed concern that if prior approval is required for drugs produced by manufacturers that do not enter into rebate agreements, "first-choice drugs will not be readily approved where second-choice inferior alternatives exist." *Id.* at 17. But the court found insufficient evidence to invalidate the prior authorization provisions on that basis in the context of petitioner's facial challenge to the Maine Rx Program. *Id.* at 14-17.

The court also rejected petitioner's argument that it would be necessary to invalidate Maine's prior authorization provisions if they advanced no Medicaid purpose, concluding that the absence of a Medicaid purpose "does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program." Pet. App. 12-13. In addition, however, the court concluded that the Maine Rx Program does serve Medicaid purposes. The court reasoned that the Maine Rx Program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical

services,' 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." *Id.* at 13. The court also stated that "there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." *Ibid.* The court explained that, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Ibid.*

Finally, the court rejected petitioner's contention that the Maine Act is unconstitutional under the Commerce Clause. Although the court agreed with the district court that Maine was not acting as a market participant in enacting the Maine Rx Program, see Pet. App. 20, it concluded that the prior authorization provisions do not constitute extraterritorial regulation. The court observed that, unlike the state statutes invalidated by this Court under the Commerce Clause, "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect." *Id.* at 22. The court explained that "Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price," and held that "[s]imply because the manufacturers' profits might be negatively affected by the Maine Act * * * does not necessarily mean that the Maine Act is regulating those profits." *Id.* at 22-23.[3]

[3] Judge Keeton filed a concurring opinion that stressed the difficulty of prevailing on a facial challenge. Pet. App. 31-53. No action was taken on petitioner's petition for rehearing *en banc* because all but one of the active judges on the court of appeals were recused. See *id.* at 54-55. Chief Judge Torruella voted to rehear the case *en banc*. *Id.* at 55.

DISCUSSION

Review of the court of appeals' decision is not warranted, especially at this interlocutory stage of the case. The court of appeals vacated the preliminary injunction entered by the district court in the context of petitioner's facial challenge to the Maine Rx Program in advance of its implementation. The courts below may consider additional factual and legal arguments in the course of further proceedings leading up to entry of a final judgment. Furthermore, the court of appeals' decision represents the first appellate decision to address whether the Medicaid Act bars a State from subjecting drugs to prior authorization under its Medicaid program in order to reduce drug prices for *non*-Medicaid populations.

Nor is this Court's review necessary to establish a rule that state programs necessarily conflict with the Medicaid statute whenever they operate in part to benefit a non-Medicaid population. There could be situations in which a State might seek to implement a program that, unlike the Maine Rx Program, is tailored to benefit individuals who are financially needy, but not Medicaid-eligible, in order to decrease the likelihood that they would *become* Medicaid-eligible. Indeed, other States have sought approval for similar programs under the Secretary's authority to approve demonstration projects calculated to "promot[e] the objectives" of the Medicaid program, 42 U.S.C. 1315(a) (1994 & Supp. V 1999), and the Secretary of HHS, who is charged with administering the Medicaid program, is in the process of considering those requests. The Secretary should be

permitted to use the existing administrative process to develop principled distinctions between permissible and impermissible state programs before this Court addresses those questions.[4] If a circuit conflict should develop after the Secretary has reviewed those applications and developed criteria, or if issues should then persist or emerge that warrant this Court's review, the Court would have occasion to grant review at that time.

Petitioner's constitutional challenge likewise does not warrant review. The court of appeals was correct to reject the argument that the Maine Rx Program regulates extraterritorially, and that ruling does not conflict with the ruling of any other court of appeals.

1. a. The court of appeals "perceive[d] no conflict between the Maine Act and Medicaid's structure and purpose" because, even assuming that the Maine Act has no "Medicaid purpose," the Maine Act, in the court's view, does not "*conflict[]* with the objectives of the Medicaid program." Pet. App. 11, 13. That perception may well have been incorrect, but especially given the posture of the case, it does not warrant review by this Court.

Under the Maine Act, the State "shall impose [the] prior authorization requirements in the Medicaid program" on any drug manufacturer that does not enter

[4] The Secretary is exploring several avenues for making prescription drugs more available to low-income individuals, including seniors, who are not Medicaid eligible. For example, the Secretary recently announced a new initiative, known as "Pharmacy Plus," that will make it easier financially and administratively for States to obtain the Secretary's approval for demonstration projects under Section 1315 to expand prescription drug benefits to low-income individuals. See also pp. 13, 15, *infra* (discussing, inter alia, HHS approval of Illinois' prescription drug demonstration project under Section 1315).

into a rebate agreement with the State for drugs dispensed to *non*-Medicaid patients. Maine Act § 2681(7). Thus, the State program on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug that is prescribed by a physician. See Pet. App. 17.

While States participating under Medicaid must ensure that covered services will be provided in a manner consistent with "the best interests of [Medicaid] recipients," 42 U.S.C. 1396a(a)(19), that provision of course must be read in light of other provisions of the Medicaid Act that, *inter alia*, require a State to provide such procedures as may be necessary "to safeguard against unnecessary utilization" of services and to assure that payments are consistent with "efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A) (Supp. V 1999). Congress therefore has authorized States under certain conditions to impose prior authorization requirements on otherwise covered outpatient drugs. 42 U.S.C. 1396r-8(a) (1994 & Supp. V 1999); 42 U.S.C. 1396r-8(d)(5). Congress enacted those provisions so that States "would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990). Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid.

It is possible that a state prior authorization requirement might advance Medicaid-related goals. For instance, as a result of the eligibility restrictions under Medicaid, many lower-income individuals who find it difficult to pay for needed medical care are nevertheless not Medicaid-eligible. As of 1998, only 40 percent of those persons with incomes below the federal poverty level were covered by Medicaid. See Staff of House Comm. on Ways and Means, 106th Cong., 2d Sess., *2000 Green Book* 902 (Comm. Print 2000). A prescription drug discount, made possible by encouraging manufacturers to give rebates to the State, may significantly decrease the chance that such individuals will become Medicaid-eligible. Thus, had Maine tailored its Rx Program to benefit such low-income individuals, it might have been able to demonstrate that the prior authorization requirement would sufficiently advance a Medicaid purpose to be approved by the Secretary of HHS pursuant to his various authorities under the Medicaid statute.

The court of appeals suggested that the Maine Rx Program could be sustained because there was "some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." Pet. App. 13. The Maine Rx Program, however, is open to all Maine residents, regardless of financial need, *id.* at 3, and the Maine Act's statement of purposes reveals no Medicaid objective. See 1999 Me. Laws ch. 786, § A-5(3) (the law was enacted "to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefitting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare").

Indeed, the Maine Rx Program stands in contrast to the design of a demonstration project that Maine itself has been conducting with the approval of the Secretary of HHS under 42 U.S.C. 1315. See Me. Rev. Stat. Ann. tit. 22, § 258 (West Supp. 2001). Unlike the Maine Rx Program, the demonstration project (known as the Healthy Maine Prescription Program) is specifically tailored to provide prescription drug discounts to Maine residents with household incomes of up to 300% of the federal poverty level. Individuals eligible for benefits under this demonstration project would have little incentive to enroll in the Maine Rx Program because the demonstration project appears to offer greater benefits. Thus, as a practical matter, the Maine Rx Program essentially targets persons whose income is in excess of 300% of the federal poverty level. Based on the record to date and in the absence of actual experience under the Maine Rx Program, no Medicaid purpose appears to be served by a state program focusing on that population.[5]

b. Petitioner urges (Pet. 22) this Court to grant certiorari because other States are considering passing drug rebate programs similar to the Maine Rx Program. We do not yet know whether a significant number of States will pass such legislation, however, and the decision below is the first appellate decision to address the validity of such a law under the Medicaid Act. Contrary to petitioner's contention (Pet. 11-13), the decision below does not conflict with the D.C. Circuit's decision in *PhRMA* v. *Thompson*, 251 F.3d 219

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[5] Maine's demonstration project has been upheld against a challenge by petitioners. See *Pharmaceutical Research & Mfrs. of America* (*PhRMA*) v. *Thompson*, 191 F. Supp. 2d 48 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir.).

(2001), which addressed a different, although related, set of issues under a different statutory provision of the Medicaid Act. In that case, petitioner successfully challenged a Vermont demonstration project under which the State required drug manufacturers to pay rebates for drugs purchased by certain individuals who were otherwise not covered by the State's Medicaid program. The court's analysis turned on the meaning of a Medicaid provision stating that manufacturers owe rebates only for drugs "for which payment was made under the State plan." See *id.* at 226 (quoting 42 U.S.C. 1396r-8(b)(1)(A)). Although Vermont paid, on behalf of the beneficiaries of the demonstration project, a portion of the price of prescription drugs, the court determined that those payments were not "payments" within the meaning of the relevant Medicaid provision because they were subsequently reimbursed through the manufacturer rebates and thus involved no expenditure of government funds. See *id.* at 224-226.

The Vermont project at issue in *Thompson* did not rely on prior authorization requirements to encourage manufacturer rebates, and the court did not consider the question whether such requirements would be consistent with the Medicaid statute's structure and purpose. Review by this Court is therefore not necessary to resolve a conflict in the circuits.

Nor is this Court's review necessary to determine, as petitioner urges (Pet. 21-23), whether, as a general rule, States may impose requirements under Medicaid in order to serve non-Medicaid populations. As discussed above, if such a requirement were suitably tailored to serve Medicaid-related program goals, it might well be consistent with the Medicaid statute. The State of Maine, however, adopted its program unilaterally, with no involvement or approval by the Secretary, and its

program is unusual in that it uses the State's Medicaid prior-approval authority to achieve ends unrelated to the Medicaid program itself.

The Secretary of HHS, who is charged with administering the Medicaid program, is evaluating requests by other States that seek to reduce prescription drug costs by requesting the Secretary to exercise his authority to authorize demonstration projects under 42 U.S.C. 1315 and to approve state plan amendments under 42 U.S.C. 1396a(b). For instance, HHS has informed this Office that on January 28, 2002, CMS approved under its Section 1315 demonstration project authority a proposal by the State of Illinois to provide comprehensive pharmacy benefits, with primary care coordination, to senior citizens with incomes at or below 200% of the federal poverty level. And, as described above, the Secretary also has approved a demonstration project for the State of Maine. Particularly in these circumstances and in the absence of any conflict in the circuits on the question presented, this Court's review would be premature.

c. The court of appeals' rejection of petitioner's facial challenge to the Maine Rx Program under the Commerce Clause likewise does not warrant this Court's review. The decision of the court of appeals is correct on that issue, and it does not conflict with the ruling of another court of appeals.

It is well established that the Commerce Clause precludes extraterritorial state regulation, that is, state regulation of commerce that occurs outside the State's borders. See, *e.g.*, *Healy* v. *Beer Institute*, 491 U.S. 324, 336 (1989). By prohibiting extraterritorial state regulation, the Commerce Clause protects "against inconsistent legislation arising from the projection of one

state regulatory regime into the jurisdiction of another State." *Id.* at 337.

A state regulation may be impermissibly extraterritorial even if, in a narrow sense, it addresses conduct that occurs within the State. The critical inquiry is whether "the practical effect of the regulation is to control conduct beyond the boundaries of the State." 491 U.S. at 336.

Thus, in *Healy*, this Court invalidated a Connecticut statute that required beer distributors to file a statement that their Connecticut prices did not exceed the price charged by the distributor in any neighboring State. 491 U.S. at 328-329 & n.5. Although the state statute appeared to be aimed at in-state conduct, the court held it unconstitutional because it had the practical effect of precluding the distributors from reacting to different market conditions that might exist in neighboring States. *Id.* at 338. See *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 583 (1986) (invalidating a similar state statute).

Similarly, in *Edgar* v. *MITE Corp.*, 457 U.S. 624, 642-643 (1982) (plurality opinion), the Court invalidated an Illinois statute that purported to give Illinois authority to regulate interstate tender offers if the target company had certain specified connections to the State. In striking down the statute, the Court noted that it would give Illinois the power to block a corporate takeover even if takeover would not affect a single Illinois shareholder. See *id.* at 642. The plurality concluded that the Illinois law "directly regulates transactions which take place across state lines, even if wholly outside the State of Illinois," *id.* at 641, and observed that if Illinois were free to enact such legislation, other States similarly were so empowered, "and interstate commerce in securities transactions generated by tender offers would be thoroughly stifled," *id.* at 642. See also *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559, 572 (1996) ("We think it follows from these principles of state sovereignty and comity that a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other States."); *Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 619 (7th Cir. 1999) (Wisconsin could not prohibit volume discounts to an Illinois milk processor's purchase of milk in Illinois, even though the milk was originally produced by Wisconsin dairies).

The Maine Rx Program does not contravene the foregoing principles. The rebates that participating drug manufacturers would pay to Maine are triggered by the sale, in Maine, of the manufacturers' products. Although petitioner notes that most manufacturers sell their drugs to out-of-state intermediaries before the products reach Maine, see Pet. 15, the Maine Rx Program does not regulate the terms of those out-of-state transactions. Indeed, petitioner's broad reasoning would condemn a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers, such as those imposing liability on out-of-state drug manufacturers for the in-state sale of defective or unreasonably dangerous drugs or requiring that all automobiles sold in-state meet state emissions standards.[6]

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[6] For similar reasons, if the Maine Rx Program were regarded as imposing a tax on out-of-state drug manufacturers, the Program would satisfy the requirement that such a tax be applied "to an activity with a substantial nexus with the taxing State." *Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274, 279 (1977). The court of appeals did not address that issue because petitioner did not present it to the district court. Pet. App. 27 n.11.

Nor does the Maine Rx Program directly link the amount of the rebates to the rebate amount paid under the Medicaid program pursuant to a national rebate agreement entered into by the Secretary of HHS pursuant to 42 U.S.C. 1396r-8. To be sure, the Maine statute directs the state commissioner, in "negotiat-[ing]" the amount of the rebate, to "take into consideration" the rebate calculated under the Medicaid program, and to use his "best efforts" to obtain a rebate equal to or greater than that amount for non-Medicaid beneficiaries. See Maine Act § 2681(4). As the court of appeals concluded, however, those provisions do not purport to regulate or control the amount of rebates paid out-of-state. See Pet. App. 23; see also W. Phelps, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 Alb. L. Rev. 243, 266 (2001) ("The Maine statute does not link Maine's prices to any other state and thus does not interfere with competition in the marketplace between manufacturers."). Accordingly, the court of appeals' ruling that the Maine Rx Program comports with the Commerce Clause does not warrant further review by this Court.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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